

510(k) Summary

[as required by 807.92(c)]

DEC 22 2010

A. 510K Number

K102281

B. 510(K) Preparer

Company name: Business Association Co., Ltd.

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C. 510(K) Owner

INAREX CORPORATION

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D. Regulatory Information

1. Classification Name: Table, physical therapy, multi function
2. Common/Usual Name: Thermal massage bed
3. Proprietary Name: Thermal massage bed (2D-GX)
4. Classification /Product Code: Class II / JFB (21 CFR 890.5880)

E. Identification of the legally marketed device

1. Classification Name: Table, Physical therapy, Multi function
2. Common/Usual Name: Thermal massage bed
3. Proprietary Name: Thermal massage bed (2D-LX)
4. Classification /Product Code: Class II / JFB (21 CFR 890.5880)
5. 510(K) Number: K080554

F. Intended Use

Thermal Massage Bed (2D-GX) is a device intended to provide patients with muscle relaxation therapy by delivering heat and soothing massage.

Additionally, the lamps provide topical heating.

- temporary relief of minor muscle and joint pain, and stiffness
- temporary relief of minor joint pain associated with arthritis
- temporary increase in local circulation where applied
- Relaxation of muscles

G. Device Description

This device is intended to provide patient with muscle relaxation therapy by delivering heat and soothing massage. This device has auto mode, and four custom modes to massage the back and apply heat to calves and thighs. For the upper mattress, there are germanium

ceramic roller controlled left and right by motor. Germanium ceramic roller also can be controlled up and down. The users can choose the auto mode or custom mode by using the remote control and the remote control has the FND screen which shows the temperature and LED which indicates operation condition.

H. Technological Characteristics:

Feature		Specification
Upper and Lower body mattress	Temperature setting	30°C/35°C/40°C/45°C/50°C/55°C/60°C/65°C/OFF.
	Vertical control	Operated by using up/down photo sensor
	Horizontal Control	Operated by using Hall effect sensor
AUX8	Temperature setting	30°C/35°C/40°C/45°C/50°C/55°C/60°C/65°C/OFF.
Time setting		15/30//45/60/15 (Minutes)
Mode		Auto mode Custom mode 1,2,3,4
Weight		75Kg
Dimensions		2,000mm(L)x 700mm(w) x 550mm(H)

I. Substantial Equivalence Comparison

This device, INAREX CORPORATION, thermal massage bed (2D-GX) and predicate device are substantially equivalent and have the same intended use. Technological and performance difference do not raise any new questions of safety or effectiveness. Comparison analysis, including comparison tables, of the subject device versus the predicate device is provided as below:

Model Name	2D-GX	2D-LX
510(K) Number	None yet	K080554
Classification	Table, physical therapy, multi function (Class II), 21 CFR 890.5880	Same
Intended Use	Thermal Massage Bed (2D-GX) is a device intended to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, the lamps provide topical heating.	Same
Indications	Thermal Massage Bed (2D-GX) is a device intended to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, the lamps provide topical heating.	Same

		-temporary relief of minor muscle and joint pain, and stiffness -temporary relief of minor joint pain associated with arthritis -temporary increase in local circulation where applied -Relaxation of muscles	
Standards		IEC60601-1 IEC60601-1-2 IEC60601-2-38	Same
Rated supply volt		120V~/230V~	Same
Supply Frequency		50/60Hz	Same
Power Consumption		Max.230VA	200W
Dimensions		2,000mm(L)x700mm(W)x550mm(H)	2,000mm(L)x700mm(W)x700mm(H)
Weight		75Kg	88Kg
Safe Working Load		Max.170Kg	Same
Use temperature		30°C~65 °C	Same
Upper body mattress	General Description	Programmed to apply thermal massage to upper body by operating germanium roller.	Programmed to apply thermal massage to upper body by operating jade roller.
	Up/Down	Rack Gear type	Cam Follower type
	Up/Down limit	-Photo Sensor applied -LED for checking the working condition	Mechanical limit switch
	LAMP	Same	12v 10w
	Left & right transmission limit	-Hall effect sensor applied -LED for checking the working condition	Mechanical limit switch
	Massage roller	Germanium ceramic	Jade
Lower body mattress	General Description	Apply heat to the lower body on the lower body mattress. -For the component of lower mattress, there are heating film protection , heating panel, heating film protection, non woven fabric, Germanium ceramic and net material (written in order)	Give thermal massage therapy by operating jade roller.
	Heating panel	-Two heating film protection protect heating panel back and forth	Not Applicable
Control panel		It contains terminal for the power supply, auxiliary hand-held unit, remote control, and connecting cables.	Same

Auxiliary handheld unit	General Description	Can apply heat directly to the body by one set of germanium hand-held unit	Can apply heat directly to the body by two sets of jade hand-held unit.
	2 Aux	Eliminated	Applied
	8 Aux	The caps are made of Germanium ceramic	Applied The caps are made of Jade
Outer Cover		Removable and hand washable for easy cleaning	Same
Remote controller	General Description	A user friendly remote control that controls all functions automatically or manually.	Same
	Buttons	Rubber pad type (similar to TV remote control)	Sticker pad type
	Temp./Time	Display area is wider than 2D-LX	
	Repeating term	Repeating term is divided into four terms.	None
	Height control	(L1, L2, L3) 3 Steps, height is measured from the head side (upper side).	(L1, L2, L3)3 Steps, height is measured from the lower side.
Software		MCU Atmega32	MCU Atmega128
		-Due to change of MCU Atmega32 to MCU Atmega128, program size 2D-LX (75KB) has been changed into 2D-GX (95KB). In addition, due to the change of I/O from the chip itself, firmware is changed and sources of each part are distinguishable and those make the device modifiable.	
Feature		Thermal method is modified by using Germanium ceramic and heat on the lower part.	
Risk analysis	Potential new hazard introduced by the modification	-Heat transfer rate of germanium ceramic is higher than that of jade and this makes temperature goes higher than 2D-LX. -There is no control system for overload of motor	
	Causes of the hazards	-Temperature of upper germanium roller is higher than that of jade roller. -If there is no bimetal and control system, temperature goes up to 120°C -Surface temperature of 8 Auxiliary handheld unit is higher than 2D-LX. -If the upper body left & right limit sensor(hall sensor) is bad, it is hard to control(Activation is checkable by naked eyes) -There is no other control system for motor load. (Even if there is large load while motor is activating, output keeps coming out.)	
	Potential effects on the user	There is possibility of burning by germanium ceramic roller or cam.	
	The severity	4	

	level	
	The actions taken to mitigate the risks	<ul style="list-style-type: none"> -Temperature is controlled by temperature sensor -If the temperature control system is bad, power turns OFF by bimetal. -Temperature control of lower heat is designed to make lower temperature than actual temperature. (Checking temperature variation) -If the Hall effect sensor and Photo sensor are not connected, error occurs and system stops. -System turns OFF when the remote control and 2D-GX is separated. -Motor should go to head side, and up/down position should be down side when the device is off. Device does not turn off if it is not initialized.

J. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

The Model 2D-GX thermal massage bed has been tested to and meets the requirements of the following standards.

IEC60601-1 :88+A1:91+A2:95 Medical electrical equipment—Part1:General requirements for safety

IEC 60601-2-38:1996+A1:1999Medical electrical equipment Part2: Particular requirements for the safety of electrically operated hospital beds

IEC60601-1-2:2007 Medical electrical equipment—Part1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests.

K. Discussion of Clinical Tests Performed:

The performance test was performed in order to show the safety of the device and to show the device can make the therapeutic range (40~45°C) from the users' skin surface temperature. By testing 30°C and 65°C (minimum and maximum of the device temperature setting) for 5 people, the device is able to elevate skin surface temperature from normal baseline temperature to the therapeutic range (40~45°C) when the device activated by 65°C setting. And for 30°C setting, device has not been shown to provide a therapeutic effect and is indicated for comfort warming only.

L. Conclusion:

The non-clinical testing and clinical study results demonstrate that the 2D-GX, thermal massage bed is safe, accurate. It also demonstrates that the 2D-GX, thermal massage bed is substantially equivalent to the predicate device, 2D-LX, currently sold on the U.S. market.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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DEC 22 2010

Re: K102281

Trade/Device Name: Thermal Massage Bed, Model No. 2D-GX
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-function physical therapy table
Regulatory Class: Class II
Product Code: JFB
Received: November 30, 2010

Dear Ms. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

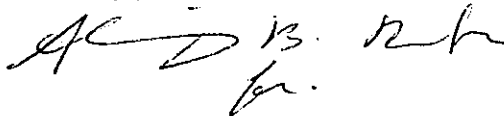
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC 22 2010

510(k) Number (if known): K102281

Device Name: Thermal Massage Bed Model No. 2D-GX

Indications for Use: Thermal Massage Bed (2D-GX) is a device intended to provide patients with muscle relaxation therapy by delivering heat and soothing massage. Additionally, the infrared lamps provide topical heating for:

- Temporary relief of minor muscle and joint pain, and stiffness
- Temporary relief of minor joint pain associated with arthritis
- Temporary increase in local circulation where applied
- Relaxation of muscles

Prescription Use _____

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use x

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

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